

## **DETAILED ACTION**

### ***Response to Amendment***

1. This action is responsive to the Amendments filed August 27, 2008. Claims 1-14, 16-21, 23, 24, 26 and 29-35 are pending. Claims 1, 2, 8, 11-14, 16-19, 24, 26 and 30 have been amended. Claims 15, 22, 25, 27 and 28 have been cancelled. Claims 31-35 are new.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27, 2008 has been entered.

## **EXAMINER'S AMENDMENT**

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Greg Maurer (Registration Number 43,781) on September 4, 2008.

The application has been amended as follows:

**IN THE CLAIMS:**

**Claim 12**, line 11 as filed July 28, 2008 states "via the measurements"; has been amended to recite --via the remaining measurements--.

***Allowable Subject Matter***

4. Claims 1-14, 16-21, 23, 24, 26 and 29-35 are allowed.

5. The following is an examiner's statement of reasons for allowance:

Wittwer et al. (US Patent 6,503,720) teaches a method for quantification of an analyte. Wittwer teaches taking an nth derivative of an amplification curve or array and using the derivative to determine a maximum, minimum, or zero value of the derivative to calculate the initial concentration of the nucleic acid. Wittwer does not teach finding a usable portion of the sigmoid curve with bounds determined by a second derivative and further finding whether an observation lies within that usable portion.

Becking ("On the Analysis of Sigmoid Curves") teaches analyzing sigmoid curves. He teaches the sigmoid curve often represents a biological expression for growth, wherein the second derivative is the growth-acceleration. Becking does not teach finding a usable portion of the sigmoid curve with bounds determined by a second derivative and further finding whether an observation lies within that usable portion.

Eyre (US Patent 7,373,253) teaches a multi-test analysis of real-time nucleic acid amplification. Eyre finds a confidence band interval for gathered fluorescent

measurements. A sliding window is used to find the second derivative. Figures 5 and 6 of Eyre illustrate the operations performed. Eyre does not teach finding a usable portion of the sigmoid curve with bounds determined by a second derivative and further finding whether an observation lies within that usable portion.

Claims are allowable over the prior art because calculating the concentration of a substance in a test sample including after a second derivative is calculated for a standard sigmoid curve, finding a first point on the standard sigmoid curve via the second derivative of the standard sigmoid curve and designating the first point as a first bound; finding a second point on the standard sigmoid curve via the second derivative of the standard sigmoid curve and designating the second point as a second bound; determining a usable portion of the standard sigmoid curve as a plurality of points on the standard sigmoid curve between the first bound and the second bound; and further determining whether the at least one observation is within the usable portion of the standard sigmoid curve (as can be found in all independent claims) is not found, taught or suggested in the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. SUGLO whose telephone number is (571)272-8584. The examiner can normally be reached on M-Th from 7:30am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eliseo Ramos-Feliciano can be reached on 571-272-7925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JANET L SUGLO/  
Examiner, Art Unit 2857

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